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ESTABLISHMENT OF LIMITS ON PRICES OF DRUGS PROCURED BY THE DEPARTMENT OF VETERANS AFFAIRS

NOVEMBER 25, 1991.—Ordered to be printed

Mr. MONTGOMERY, from the Committee on Veterans' Affairs, submitted the following

REPORT

[To accompany H.R. 2890 which on July 15, 1991, was referred jointly to the Committee on Veterans Affairs and the Committee on Energy and Commerce]

[Including cost estimate of the Congressional Budget Office]

The Committee on Veterans' Affairs, to whom was referred the bill (H.R. 2890) to establish limits on the prices of drugs procured by the Department of Veterans Affairs, and for other purposes, having considered the same, reports favorably thereon without amendment, by unanimous voice vote, and recommends that the bill do pass.

INTRODUCTION

On September 11, 1991 the Subcommittee on Hospitals and Health Care held a hearing to receive testimony about the reasons for, and implications of, sharp increases in drug prices to the VA in the preceding months. Testimony was received from Anthony J. Principi, Deputy Secretary, Department of Veterans Affairs (VA), and Gerald Mossinghoff, President, Pharmaceutical Manufacturers Association. Testimony focused on pharmaceutical pricing practices which became manifest after January 1, 1991, the effective date of section 4401 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 (titled "Reimbursement for Prescribed Drugs") in apparent response to that law. The Committee also heard testimony on the impact and magnitude of those price increases on veterans who seek medical care from the VA, and its current and future pharmacy and medical care budgets. The hearing ultimately focused on the need for remedial legislation aimed at establishing a framework under which VA could win reasonable prices for pharmaceuticals

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such as it had negotiated with many manufacturers prior to OBRA's enactment. In that regard, the Committee received testimony on H.R. 2890, a bill to establish limits on the prices of drugs procured by the VA.

On October 2, 1991 the Subcommittee met and recommended H.R. 2890 to the full Committee. The full Committee met on November 13 and ordered, by unanimous voice vote, that H.R. 2890 be reported to the House.

The bipartisanship underlying this proposal attests to the Committee's profound concerns. In essence, the Committee believes that, absent the enactment of legislation which would result in rolling back prices VA pays for needed pharmaceuticals to levels comparable to those in place prior to OBRA, veterans will suffer. As graphically depicted in this report, the veteran has become the ultimate and unwitting victim of pharmaceutical companies' circumventing Congress' intent by raising VA prices to protect their profit margins. In the words of VA's Deputy Secretary, veterans "are getting hurt" and, absent such legislation, "are going to be denied care. That's the bottom line."

Summary of Reported Bill

H.R. 2890 would:

1. Provide that the Secretary of Veterans Affairs may not make any payment for covered drugs and biological products to a manufacturer unless the price charged by the manufacturer to the Department of Veterans Affairs is determined in accordance with an agreement entered into between the Secretary and the manufacturer that meets the requirements of section 1927(a)(5) of the Social Security Act (as added by subsection (b)(2)).

2. Amend section 1927(a)(1) of the Social Security Act to require manufacturers to sell VA covered drugs at prices which are either negotiated by the parties or are set in accordance with a formula set in a new section 1927(a)(5)A)(1) of the Social Security Act.

3. Provide that under such a formula, prices may not exceed the applicable price for a drug charged VA as of September 1, 1990, increased by an inflation factor calculated quarterly after April 1, 1991.

4. Provide that any VA-procured drug or biological product (a) purchased under a depot contracting system, or (b) listed on the Federal Supply Schedule on or after January 1, 1990 is subject to the renegotiation or price-limitation provisions of this Act.

5. Exclude prices of prescription drugs procured by the federal government from the determination of "best price" for purposes of calculating Medicaid rebates for drugs procured on or after October 1, 1991.

6. Require the Secretary of Veterans Affairs to conduct a study of the effects of this Act on the costs and availability of drugs and biological products for VA and submit a report to the Committees on Veterans' Affairs of the House and Senate not later than 1 year after the date of enactment together with a report on the status of contract negotiations between the Secretary and manufacturers of covered drugs and biological products, including a description of

any negotiations that are not resolved at the time the Secretary submits the report.

BACKGROUND

In October of 1990, Congress passed and the President signed into law the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). Section 4401 of that Act, "Reimbursement for Prescribed Drugs", established as of January 1, 1991, a mechanism aimed at providing state Medicaid programs with discounts in the form of rebates for prescription drugs. This provision was an outgrowth of legislation proposed previously in the 101st Congress to control Medicaid pharmaceutical expenditures.

At its heart, the law provides that the federal government will not grant federal Medicaid matching funds (federal financial participation) to states for payment for the drugs of a manufacturer which does not agree to provide each State Medicaid program with a schedule of rebates for its products. Each State, as a condition of the rebate agreement between a manufacturer and the Secretary of Health and Human Services, must allow payment for all of the manufacturer's covered outpatient drugs that are prescribed for medically accepted indications. The law calls for quarterly rebates.

Under the law, the rebate (in the case of non-generic drugs) is to be the greater of (1) a percentage (which increases from year to year) of the average manufacturer price (AMP) or (2) the difference between AMP and the "best price" for the drug. Average manufacturer price is defined to mean the average price paid by wholesalers for a drug for distribution to retail pharmacies. "Best price" is defined in the law to mean " . . . the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government) . . . "

The law thus provides a vehicle for providing Medicaid programs with the same "best price" discounts which other large-buying entities secured through negotiation. The measure was anticipated to save the Medicaid program $3.4 billion over the next five years. In making such projections, however, the Congressional Budget Office failed to identify the impact its provisions would have on other federal programs. That impact stemmed from the law's reliance on "best prices" to determine Medicaid discounts.

While the law exempted the prices of drugs purchased through VA-operated depots (storage and distribution centers), for example, from the best-price benchmark, it did not specifically exempt the prices of pharmaceuticals set in the VA-administered Federal Supply Schedule. The legislative record associated with the OBRA provisions reflected a view held by some that in many cases the prices of drugs procured by the Department of Veterans Affairs (VA) through the Federal Supply Schedule (FSS), which it administers, were the lowest or near the lowest available. Significantly, the law did not include language which had been an element of earlier measures, and would have anchored "best prices" by tying increases to the consumer price index.

Impact on VA

From VA's standpoint, the effect of this law has been harsh. In the absence of a mechanism to guard against unreasonable increases in "best prices", manufacturers moved quickly to increase their prices. VA was particularly hard hit.

The VA, which in 1990 was a $700 million buyer of pharmaceuticals annually, procures drugs through several distinct mechanisms. The first, the depot system, is primarily for high-use pharmaceuticals which VA stores at, and distributes from, depot-warehouses. The depot system accounts for approximately 25 percent of VA drug purchases. When VA chooses products for depot purchase and distribution, it negotiates a price, guaranteeing a nationwide purchase volume, and the product is delivered to VA-owned and operated depot sites. From there, VA is responsible for distribution to VA medical centers.

Secondly, VA has begun to procure certain drugs through so-called single award contracts. These are contracts entered into by VA and a manufacturer, for the manufacturer to become VA's single supplier of an extensively used pharmaceutical product. Using a competitive bidding process in this manner, VA has beem able to obtain very favorable prices for selected pharmaceutical products.

A third mechanism for pharmaceutical procurement is the VA-administered Federal Supply Schedule. The FSS, which accounts for approximately fifty percent of VA drug purchases, is a published list of all drugs available to VA medical centers from manufacturers, at prices negotiated by VA authorities. In addition to VA, the Department of Defense (DoD), Public Health Service, the Indian Health Service, and the Bureau of Prisons all have authority to purchase through FSS contracts and regularly do so, since the negotiated prices traditionally have been significantly lower than are available elsewhere. In addition to VA's purchases of in excess of $300 million in pharmaceutical products through the FSS annually, sales of FSS pharmaceuticals to DoD total approximately $225 million annually.

Under circumstances where the need for particular drugs cannot adequately be met through any of the usual sources, VA medical centers may, and from time to time must, purchase such drugs on the open market. As would be expected, the cost of purchasing low volumes on the open market is significantly higher than purchasing through one of VA's prenegotiated avenues.

At the September 11 hearing conducted by the Committee, Deputy Secretary Principi described sudden and sweeping pharmaceutical price increases which many manufacturers imposed on VA early in 1991. "While we had anticipated some cost shifting to result from this legislation, we were surprised by its sheer magnitude," Principi reported. The cost-shifting he described was magnified in substantial part by the fact that the five-year Federal Supply Schedule contracts (which permit a manufacturer to raise its prices annually up to the level of the consumer price index) all expired on December 31, 1990, just as the OBRA provisions became effective, leaving VA particularly vulnerable.

The pharmaceutical industry has asserted, in effect, that the laws of the marketplace forced companies to increase VA prices. Its representatives argued that from a business standpoint the drug companies could not feasibly provide to some fifteen percent of their market (Medicaid) the discounts provided to an entity which represented a significantly smaller percentage. This assertion was made at the September 11, 1991 hearing, held by the Hospitals and Health Care Subcommittee, during which Gerald Mossinghoff, President of the Pharmaceutical Manufacturers Association stated that *"I think OBRA has clearly caused an increase in prices to VA FSS. I have no reason to doubt that . . . I believe it's because, by giving those discounts to VA, the companies are then forced to give those same discounts to 15 percent of their market."* Mossinghoff maintained that when faced with opening up fifteen percent of their market (Medicaid) to the discounts received by one percent of their market (VA), most drug companies chose to eliminate the discounts they had previously offered.

OBRA alone cannot be blamed for industry behavior, however. Some companies imposed substantial price increases on the prices of drugs purchased through the VA depot system. Since depot prices are exempt under OBRA from the rebate calculation, manufacturers can hardly assert that pricing practices were purely defensive. By way of illustration, and as brought out at the Subcommittee hearing, one manufacturer increased the price to the VA depot of nitroglycerin, a medication for angina, from 66 cents (.4mg/100 units container) in 1990 to $2.73 in 1991, an increase of 314 percent. The same company hiked the depot price at which it sells Dilantin, an important drug for the treatment of most seizure disorder patients, from a 1990 price of $17.71 (100 mg./1000 units) to a 1991 price of $45, an increase of 154 percent. The FSS price for the same drug went up 185 percent.

FSS prices also saw marked increases. One manufacturer hiked its FSS price for cholestyramine powder, a drug to reduce cholesterol, by more than 80 percent. A major VA supplier boosted its FSS price for heavily used human insulin by almost 41 percent. VA has seen the FSS price of Lopressor, a drug for the treatment of certain cardiac problems, more than double. The FSS price of Procan, medication for the treatment of cardiac arrythmia, was increased by a staggering 350 percent, while the price of Pamelor, a drug used in treating psychiatric patients, was hiked by almost 80 percent.

Significantly, these and other companies also refused to sell VA certain drugs through the Federal Supply Schedule any longer, forcing VA to purchase them at substantially higher prices from wholesalers. Such action, for example, resulted in a price hike for VA in the cost of vials of Prolixin from an FSS price in 1990 of $6.54 to a cost of $79.62, an increase of more than 1100 percent.

In order to assess the impact of price increases following enactment of OBRA, VA undertook a comprehensive study of its cost and utilization of pharmaceutical items procured through both its depot system and through the Federal Supply Schedule. Secretary Principi presented the findings of that study, based on data compiled as of September 1, 1991, at the hearing. Since its aggregate drug procurement costs and utilization information is not readily

available from within existing databases, the Department developed databases. A database for 1990 and 1991 FSS prices was created representing over 12,000 line items. The Department collected utilization data from 119 VA medical centers using actual outpatient prescription dispensing information. National utilization projections were extrapolated based on the percentage of annual prescription fills that the respective medical centers represented. Ultimately, VA projected cost impact on the basis of an extrapolation of its most heavily used drugs. Analyses were also done on the impact of depot price increases, and increased costs resulting from manufacturers deleting items from the FSS. In all, VA's study projected a cost impact of at least $117 million annually based on its analysis of price changes and actual use of pharmaceuticals. Adjusting for inflation, this represents additional costs to VA of at least $60 million annually.

The real impact of these price increases on VA has yet to be felt. For one, the increases generally did not go into effect until April 1, 1991. Secondly, it was not until later in the fiscal year that many medical centers had to replace inventory at these higher prices. Nevertheless, the Comittee received correspondence from many veterans who wrote to complain that they had received "Dear Veteran" letters informing them that as of a specified date their VA medical center would discontinue filling outpatient prescriptions for specified drugs as an economy measure. Some centers responded to the pharmacy budget dilemma which these price increases posed by substituting lower cost drugs for higher cost medications or even by denying outpatient medications to nonservice-connected veterans altogether.

Veterans who are dependent on the VA health care system and who have been affected by these cutbacks often had no inkling of the source of the problem. But they have written to provide the Committee their deepfelt concerns over letters from VA advising patients of the need to "take drastic actions" to limit their receipt of prescription drugs "as we work through our extreme financial crisis". By way of illustration, one veteran wrote "I personally am appalled that the U.S. Government does not have enough money to furnish disabled veterans with the medication that their physicians have determined is best for their care for their service-connected disabilities. In my own case, I have previously tried the alternative drugs [substituted as an economy measure] and they are not as effective and cause more side effects." While some hospitals limited their cuts to the nonservice-connected, the Committee learned that even 100 percent service-connected veterans were not necessarily assured of immunity from the impact of pharmacy budget problems. As one such totally disabled veteran wrote, "I had to substitute [for] doctor prescribed medication . . . what the VA already carried instead of medication that was better. Now they can not supply this and offer instead an over the counter medication . . . I do not believe this is indicative of what you or the American people expect from a grateful nation for their veterans."

Secretary Principi underscored the dilemma: "There was no way to have foreseen this dramatic rise in pharmaceutical prices when we developed the medical care budget for fiscal years 1991 and 1992." An expert witness accompanying him, Ms. Louise Rodriguez,

the VA's chief of clinical pharmacy/quality management, explained that from a clinical perspective there is very little VA can do to achieve additional economies: " . . . while we can go back and try to remove "me too" drugs from the formularies, there aren't a lot of those." In sum, Principi noted, "the cost impact of OBRA is so severe that it cannot be dealt with" administratively. As a result, he said, "we're just going to have to cut back in certain areas, and if that means cutting programs, we'll have to cut programs. Close beds if necessary. But somehow, the VA will have to absorb at least $60 million. We have a very tight budget."

This shortfall is particularly onerous in light of the fact that this financial impact was not factored into the VA's FY 1992 budget. As a result, it became apparent that VA would be forced to take precious medical care dollars away from needed services in order to address the pharmacy budget dilemma.

The Committee has learned that VA did attempt to mitigate the anticipated budgetary impact of OBRA. The Department attempted to shift new drug contracts, to the extent feasible, to the procurement avenues which had been exempted from "best price" calculations under the law, "depot" and "single award" contracts. The law directs the Secretary of Health and Human Services to define those terms. Under those definitions, as promulgated for the Secretary by the Health Care Finance Administration (HCFA), however, manufacturers expressed unwillingness to offer low bids. The Committee has learned that that resistance was based on the inexact, "at best ambiguous" character of HCFA's definitions. The Committee understands that the Departments of Veterans Affairs and Defense (which *unlike HCFA*, do procure pharmaceuticals) attempted in many forums and on many occasions to propose more precise, workable definitions. HCFA has yet to respond satisfactorily to these VA and DoD efforts. Thus, approximately one year after OBRA's enactment, HCFA has yet to provide workable definitions called for by law. As such, that agency has impeded efforts of other Federal departments to use effectively procurement avenues specifically recognized and provided for under OBRA. Elimination of this obstacle certainly would not resolve the pharmaceutical pricing and resultant budget problem facing VA; it has made it even more severe, however.

As noted, the effects of the budget shortfall triggered by OBRA have already been experienced throughout the system. During the latter part of the fourth quarter of fiscal year 1991, many VA medical centers, some temporarily, stopped providing certain pharmaceuticals to veterans seeking care. Deputy Secretary Principi acknowledged the scope of the problem in his testimony at the September 11th hearing. He stated *"without some relief, additional funding relief, it will mean the curtailment of some services throughout the Nation . . . outpatient care, inpatient care, longer waiting lines. Clearly, hospital directors will have to make decisions on how to manage their facility, and without the dollars to buy the drugs, they are going to have to cut back on the delivery of health care . . . I have spoken with enough hospital directors now who I respect, who tell it straight to me, that we're getting hurt by this legislation and ultimately veterans are getting hurt because they're going to be denied care. That's the bottom line."*

The Committee's March 1991 report to the Committee on the Budget detailed graphically the significance of imposing new costs onto the VA health care system. A decade-long pattern has seen VA hospitals absorb cost increases and new program obligations in the face of virtually straight-lined health care budgets. The result has been a decline in service to the veteran–in the form of ever-thinner staff to patient ratios, increased waiting times for needed treatment, delays or denials of care, and inability to replace needed medical equipment or hire needed clinicians.

Goals of OBRA Frustrated

Pharmaceutical manufacturers have asserted, and its industry representative said again at our September 11 hearing, that OBRA dictated a need on the part of manufacturers to protect themselves. It appears, however, that at least some of the industry's pricing practices reflect "gaming" strategies, not self-defense. Recent commentary in the journal *Health Affairs* illustrates this phenomenon, and highlights the disproportionate impact which these practices have had on entities like the VA. "Given this rebate schedule, pharmaceutical manufacturers have powerful incentives to raise their best prices so that the spread between best price and average manufacturer price is as small as possible. This pricing strategy not only would yield a smaller rebate paid by manufacturers to state Medicaid programs, it also would shift some of the costs of Medicaid rebates to customers who previously purchased their prescription drugs at or near the manufacturer's best price." (Michael R. Pollard and John M. Coster, "Update", *Health Affairs*, Summer 1991, pp. 198-9)

The Inspector General of the Department of Health & Human Services conducted a review of the impact of the law on drug expenditures and implicitly confirmed the observations reflected by the "Update" authors. In a September 25, 1991 report to the Administrator of the Health Care Financing Administration, the IG documented the escalation of drug prices and warned of two adverse effects: *"First, the increases in the best prices may result in Medicaid not achieving the full estimated savings anticipated by the enactment of OBRA 90. Second, price increases may also cause drug costs to increase for other Government programs and for the private sector purchasers."* Based on the pattern of pricing increases experienced, the IG projected that Medicaid programs might not realize as much as $95 million in earlier-projected savings in calendar year 1991.

Congress, in enacting OBRA, apparently anticipated the possibility of price increases, and specifically provided a mechanism to monitor price changes and warn it accordingly. Thus, the law calls on the Comptroller General to report annually by not later than May 1, on "changes in prices charged by manufacturers for prescription drugs to the Department of Veterans Affairs, other Federal programs", and others. GAO failed to issue a report until September. Its report, however, reflects no effort to gather data from any source other than VA and DoD. GAO apparently took an extensive amount of time to assemble preliminary data which is drawn entirely from the two Departments. GAO's reluctance to draw conclusions, other than implicitly to acknowledge that VA

and DoD have sustained substantial price increases since OBRA's enactment, appears to reflect the ineffectual, poorly targeted character of its fact-finding effort.

Remedial Action

As noted, shortly after OBRA's pharmaceutical provisions took effect, many drug manufacturers imposed sweeping price increases on an array of FSS pharmaceuticals which, prior to OBRA, VA had procured at substantial discounts. These pricing actions increased costs not only to VA, but to DoD and other federal entities, which have procured drugs through the VA-administered Federal Supply Schedule.

Despite a temporary grace period for VA in which some manufacturers voluntarily maintained last year's FSS prices for the first quarter of 1991, VA is reportedly now paying prices which, on average, are more than 20 *percent higher than* last year and up to 70 percent higher for items deleted from the Federal Supply Schedule. While inflation in drug prices has historically been high and could account for some eight percent of these price increases, it is inescapable that the enactment of OBRA has been the primary catalyst to the price increases VA is facing.

Efforts to resolve administratively the problem of these sudden, unbudgeted new costs have not borne fruit. By way of example, early this year, the Committee wrote to the Secretary of the Department of Health and Human Services asking that he exercise his authority to exclude FSS from the definitions of "best price" in writing the regulations for the new law. The Secretary responded, in essense, that under the Department's reading of the law, he lacked authority to do so. The Committee also appealed to the Office of Management and Budget (OMB), predicting the sweeping price increases. In so writing in a letter dated January 4, 1991, the Committee assumed that surely OMB would not support, nor was it Congress' intent to attempt to achieve Medicaid savings at the expense of VA, DOD, and other federal agencies. OMB's response, four months later, offered no solution, however.

The leadership of this Committee saw the need for legislation to remedy the problem, and, accordingly, introduced H.R. 2890. The Secretary of Veterans Affairs himself acknowledged a need for legislation, and so advised the Chairman of the Committee on Energy and Commerce in a letter of August 22, 1991: "Clearly, some mechanism needs to be made available to assist VA in controlling its pharmaceutical expenditures, while at the same time allowing VA to continue to provide medically necessary pharmaceuticals to patients. Several legislative proposals have been introduced in an effort to provide some relief from the unprecedented cost increases experienced by the federal government. Given that the OBRA provision indirectly encourages price increases to VA, *stabilization of prices at the pre-OBRA levels and a restoration of marketplace conditions that would allow VA to negotiate unencumbered with manufacturers for fair prices would be indicated.*" (Emphasis added.) It is noteworthy that the Secretary is clearly describing the core provisions of H.R. 2890 in his August 22nd letter. In testifying before this Committee on September 11th, VA's witnesses had clearly been constrained by instructions from the Administration. Secre-

tary Principi acknowledged, however, his own agreement with the central provisions of H.R. 2890.

It is noteworthy that other legislative formulas have been proposed. HHS' IG called on HCFA to submit a legislative proposal "to reestablish best prices using October 1990 prices and restricting future increases in best prices to increases in the CPI-U from October 1, 1990 to the month before the calendar quarter of the rebate." This concept is similar to the mechanism employed in H.R. 2890. A September 1991 staff report of the Senate Special Committee on Aging called, in pertinent part, for the enactment of legislation to protect federal purchasers such as the VA, the Department of Defense, and community health centers from excessive drug price inflation "that meets or exceeds the inflation protection now being given to Medicaid."

Section 519 of the recently enacted VA, HUD and Independent Agencies Appropriations Act for Fiscal Year 1992, Public Law 102–139 (H.R. 2519) adopts an approach which the Pharmaceutical Manufacturers Association advised this Committee it "would not object to." Its central element provides that regardless of any other law "prices for drugs and biologicals paid by the Department of Veterans Affairs, and prices for drugs and biologicals on contracts administered by the Department of Veterans Affairs, shall not be used to calculate Medicaid rebates paid by drug and biological manufacturers." The law directs the Secretary to negotiate or renegotiate contracts with the view of achieving prices comparable to or below pre-OBRA prices. But, by its terms, the provision would not remain in effect beyond June 30, 1992, and would "sunset" earlier if Congress before that date enacts "into law legislation concerning the price of drugs and biologicals paid by the Department of Veterans Affairs."

While this formula puts a time-limited spotlight on the manufacturers' pricing to VA, there is no assurance that the invitation such language provides for *short-term* price rollbacks would be accepted. To the extent it is, though, one must recognize the artificial nature of this "experiment" and the critical significance to the pharmaceutical manufacturers of knowing how many eyes will be closely watching pricing actions during this period.

In any case, the Appropriations Act clearly envisions the enactment of further legislation to remedy VA's problem. The question for this Committee is whether a given piece of legislation will remedy the problem facing VA. By way of example, prior to OBRA's enactment, the concept of indexing "best price" was attacked by the pharmaceutical industry as constituting price controls. Congress' failure to adopt a safeguard, however, led the very critics of such a mechanism to eviscerate the weaker measure their lobbying had produced.

There is reason to view proposed OBRA "reforms" skeptically, therefore. One such concept under discussion would repeal provisions of OBRA which relied on a "best price" benchmark to set rebates. In its place, such a measure would extend flat rebates to Medicaid and other federal entities. Such an approach has several flaws from the perspective of resolving VA's complex and relatively unique problem. Operating within a fixed budget, VA is particularly vulnerable to the double- and triple-digit price hikes it faced. In

that regard, it is important to recognize that VA's pre-OBRA prices often represented very substantial discounts, lower than those afforded Medicaid. Thus, to provide VA the same discount as Medicaid would generally still represent a very substantial, above-inflation price increase. On the other hand, freeing VA from any predetermined formula offers no assurance that pharmaceutical companies would voluntarily roll back prices to comparable pre-OBRA levels. The December 31, 1990 expiration of VA's long-term Federal Supply Schedule contracts forced VA into negotiating at a particularly vulnerable time new FSS contracts. With VA locked into these long-term agreements at prices more than 20 percent higher than a year ago, manufacturers have little or no incentive under a bill without a rollback provision or other enforcement machinery to renegotiate. Moreover, VA cannot unilaterally terminate those contracts. The lessons of the OBRA experience are surely that legislation which simply removes the best price "irritant" that allegedly provoked price hikes will not induce a return to inflation-adjusted or comparable pre-OBRA market prices. Moreover, to *eliminate* the use of "best price" benchmarks for computing rebates, rather than to repair the failure to anchor those prices originally, is to excuse the egregious pricing practices so fully documented this year.

Discussion of the Reported Bill

In introducing and reporting H.R. 2890, the leadership of the Committee is proposing legislation aimed at remedying the acute problems VA has faced in coping with pharmaceutical price hikes. The Committee's jurisdiction made it inappropriate for it to attempt to address pricing issues outside that domain. It is noteworthy, however, that a legislative solution to VA pharmaceutical procurement problems will also benefit the medical programs of other Departments and agencies which provide medical care and purchase drugs from the Federal Supply Schedule: the Department of Defense, the Public Health Service (including the Indian Health Service), and the Bureau of Prisons.

The Committee is of the view that legislation is needed to reverse the unintended, but nonetheless pernicious effects of loopholes in OBRA. In defining that need, the Committee concurs that a remedy must be one which encourages a restoration of price levels comparable to those in place before OBRA as well as a restoration of a level playing field on which VA can negotiate appropriate discounts.

H.R. 2890 would achieve those goals through provisions which would:

—exclude all federal prices from the calculations of "best price", thereby eliminating a loophole which had the effect of encouraging manufacturers to escalate federal prices; and

—expand the current law—which requires that manufacturers must enter into rebate agreements in order to participate in the Medicaid program—to require that manufacturers must also agree to provide drugs to VA through the Federal Supply Schedule and its drug depot system at pre-OBRA prices adjusted by an inflation factor, or pursuant to renegotiated contracts.

Industry Contentions

The Pharmaceutical Manufacturers Association (PMA) strongly objected to aspects of H.R. 2890. The Committee was warned that this bill "would cause an unwarranted and unprecedented disruption of the U.S. free-market system—at a time when free-market principles are sweeping the world—through the imposition of government price controls on one of our country's most innovative and beneficial industries." PMA asserted that the legislation "would set a dangerous precedent that could lead to the imposition of government price controls over an even larger share of the pharmaceutical market—thus seriously impeding continuing development of new and better medicines."

PMA stressed that it represents a premier high-technology industry which invests huge sums in research and development to remain innovative and competitive. It underscored that sums devoted to R&D have been steadily increasing, in part due to the uncertainty of success and the increasing costs of discovering and developing a new drug.

PMA asserts that H.R. 2890 "would constitute a far more radical and intrusive disruption of the free-market system" than OBRA, and maintains that "[n]o reason has been shown why the pharmaceutical industry should be singled out." The Association warns that enactment of this bill would lead to additional controls on drug prices, less money generated for research and development, and ultimately a slowing of pharmaceutical innovation.

Upon scrutiny, PMA's assertions and warnings evaporate. Firstly, the Committee's hearings largely rebutted the contentions that the pharmaceutical industry operates in a pure free-market environment. Manufacturers enjoy the protection of a government monopoly in the form of a patent for any new product. As noted in *Fortune*, "Drugmakers Under Attack" (July 29, 1991) "companies with an innovative drug often enjoy years without competition during which "they can price any way they want." The Congress has also enacted special laws which benefit the industry. The Orphan Drug Act of 1983, for example, provides special financial incentives to induce manufacturers to bring to market drugs for the treatment of rare disorders. Recognizing the length of time it can take to bring a drug to market, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. Provisions of that law authorize a manufacturer to file for an extension of existing patents to take account of the testing and Food and Drug Administration review periods.

As noted in a September 1991 Senate Special Committee on Aging Staff Report on the drug manufacturing industry, the pharmaceutical manufacturers receive hundreds of millions of dollars in tax credits and subsidies for researching and developing new products. In addition, the report highlights the industry as "the leading benefactor of a generous, *non-research and development* oriented tax windfall credit", the Possession's Tax Credit (provided for under section 936 of the Internal Revenue Code). The provision grants an income tax exemption for business income earned in Puerto Rico and other U.S. territorial possessions. The report cites

a Congressional Research Service estimate to the effect that this subsidy was worth $2 billion to the drug industry in 1990.

This Committee has taken no position on the merits of maintaining the structure of Governmental benefits, subsidies, and protections, which the pharmaceutical industry has clearly enjoyed, nor should it. The Committee simply notes that the industry's plea to leave undisturbed the free market within which it operates is a hollow one. The point emerges clearly in the Committee's hearing record in a colloquy between Rep. Chet Edwards and the spokesman for PMA: "[Rep. Edwards:] [w]hile you talk about the free market, the fact is that it is the Government that gives your industry the patent laws. It is the patent laws that add value or give value [to your products]." The record attests to the fact that what the industry seeks to maintain is not a free market, but the freedom to use Government-provided supports to raise prices and boost profits, even at the expense of the Government.

Certainly, the industry has been a leader in the marketplace. But that leadership manifests itself not only in R&D, but in price inflation, marketing expenditures, and profits. *Fortune* states that for "the past 30 years the drugmakers of the Fortune 500 have enjoyed the fattest profits in big business," and that "[d]uring the 1980's the average cost per prescription for established drugs climbed at double the rate of inflation." The Senate Aging Committee report finds that prescription drug price inflation was almost three times greater than general inflation from 1980–1990. During that same period, the Committee staff found pharmaceutical inflation on average rose 18.5 percent more than medical inflation, which itself more than doubled the general inflation rate.

According to *Fortune*, "marketing muscle" has been a critical ingredient in industry's profit records. At the Committee's September 11 hearing, PMA representatives evaded questions about marketing expenditures. PMA's public relations-focused emphasis on its R&D expenditures, however, masks the enormity of its sales, marketing, and advertising budgets.

The Special Committee on Aging report states:

> Because the drug industry has become very proficient in developing an excessive number of "me-too" drug products—that is, drug products that offer little or no therapeutic advance over those that are already on the market—manufacturers invest substantial financial resources on marketing to convince health professionals that their new drugs really do make a significant contribution to the drug therapy arsenal. Recent data clearly indicate that drug manufacturers continue to inflate drug prices higher and higher to pay for their lavish and expensive marketing and advertising campaigns . . . In 1991, according to the pharmaceutical industry's own data, drug manufacturers will spend one billion dollars more on marketing and advertising than it will on research and development.

The Aging Committee's report also punctures another industry assertion. It illustrates that many drug manufacturers have brought few if any innovations (vs. "me-too" drugs) to the market in recent years, and resort to frequent and excessive price in-

creases as a way to maintain profitability on drugs that have been on the market for many years and for which research and development costs have long been recovered.

In testimony before this Committee, PMA signalled that, if legislation is to be enacted, it would welcome a measure which simply exempted VA prices from Medicaid rebate calculations. Under such legislation, PMA's President stated that "that would then restore the free market rules that existed pre-OBRA 90." However, OBRA altered those "free market rules." PMA asks this Committee to take a "leap of faith" that its members would voluntarily roll back the price of pharmaceuticals to VA to pre-OBRA levels. This Committee finds no evidence to support taking such a leap. To the contrary, experience has demonstrated that even where VA prices have been exempted from rebate calculations, as in the case of VA depot prices, many companies have raised those prices to levels substantially above normal inflation adjustments.

Clearly, an exemption from the definition of "best price" alone is no solution. One may speculate on how the market would have responded *if* OBRA had included a comprehensive exemption for Federal prices. OBRA contained no such provision, however. With prices now an average of more than 20 percent higher than a year ago, simply creating an exemption now would provide no economic incentive for companies to lower prices to comparable pre-OBRA levels.

PMA urges that the Committee defer action on H.R. 2890. The Association notes that OBRA's implementation is so recent that one should await more data. This Committee, however, must balance the desirability of more comprehensive data against the damage VA and its patients suffer under the pressure of pharmaceutical price increases. In fact, Congress itself has made its own judgment on that question in passing section 519 of the VA,HUD and Independent Agencies Appropriation Act for Fiscal Year 1992, P.L. 102-139, described earlier in this report. PMA cites the Act as a reason to delay action on the bill. Clearly, however, the authors of this provision contemplated that Congress would enact legislation like H.R. 2890, and thus made provision for what they apparently viewed as temporary relief.

PMA has attacked H.R. 2890 as a bill which would fix or control prices. The Association has clearly misread the bill, and ignored the example of OBRA itself. OBRA restructured the market and the prices within it. Unfortunately, however, it created a market environment which enabled manufacturers to pass artificially increased drug costs on to the taxpayer through drastically higher prices to VA. This bill would set up a mechanism to stimulate contract negotiations between VA and pharmaceutical manufacturers. Manufacturers would be freed from being penalized economically for providing reasonable contract prices to the federal government. The bill would create the incentive for negotiations by requiring, *that in the absence of a renegotiated contract*, prices for drugs which had been procured through the Federal Supply Schedule or through VA's drug depot system (and including drugs which manufacturers had deleted from the Federal Supply Schedule in anticipation of, or after, OBRA's enactment) would be rolled back to pre-

OBRA levels adjusted by an inflation factor on a quarterly basis, beginning on April 1, 1991.

SECTION-BY-SECTION ANALYSIS

Section 1 of the bill would establish a framework for achieving limits on prices of drugs procured by the Department of Veterans Affairs. It would provide that the Secretary of Veterans Affairs may not make any payment to a manufacturer for drugs unless the price charged by the manufacturer is determined in accordance with the provisions of the bill. This section would also build on existing law, which, as amended by OBRA-90, provides that federal matching funds under the Medicaid program would not be available for the drugs of any manufacturer which has not entered into an agreement with the Secretary of Health and Human Services to provide each Medicaid program with a specific schedule of rebates for their prescription drug products. (Such an agreement is one which meets the terms of section 1927(a)(1)–(4) of the Social Security Act.)

The bill would amend OBRA-90 by adding a provision which would also condition federal matching funds under the Medicaid program on a manufacturer's entering into an agreement with the Secretary of Veterans Affairs that meets the requirements of section 1927(a)(5) of the Act (as added by section 1(b)(2) of H.R. 2890). Specifically, the bill would add a new paragraph (5) to section 1927 setting forth the framework for an agreement which meets the new requirement for federal matching funds. Such an agreement is one between the Secretary of Veterans Affairs and a manufacturer which, with respect to a drug, reflects either an inflation-adjusted roll back of the price of that drug to so-called pre-OBRA levels, or a different price negotiated by the parties after the enactment of this provision. The Committee anticipates that such a negotiated price would be a fair and reasonable one, and would often be lower than a rolled-back price, when, for example, a manufacturer's patent for a drug has expired and a generic competitor has entered the market. In some cases the acceptance of a nominally higher price might be warranted, where, for example, the manufacturer had maintained a price over the term of a multi-year contract. Any drug or biological product which is purchased under VA's depot contracting system or that was listed under the Federal Supply Schedule of the General Services Adminstration on or after January 1, 1990 would be subject to the requirements of section 1927(a)(5).

Section (2) of the bill would amend the definition of the term "best price", used in section 4401 of OBRA-90 to calculate the rebate to the State medicaid programs. Under existing law, the term means the lowest price available to any entity within the United States, including a governmental entity, but specifically excluding "depot prices and single award contract prices, as defined by the Secretary". As amended, the exclusion would be broader. *All* prices which a manufacturer provides to an entity of the federal government—depot prices, Federal Supply Schedule, single award, or other prices—would be excluded. Under that provision, the distinctions between those means of procurement and the pre-

cise definition of the respective terms would be irrelevant for purposes of calculating Medicaid rebates.

Section 2 has particular significance to pharmaceuticals which first come to market after the enactment of the bill. It is intended to assure that the VA, in negotiating to procure new drugs—which would not be covered by the roll-back protections of section 1—have the opportunity to win meaningful discounts freed of any manufacturer's claim that it "can't" give VA a favorable price because that discount would have to be provided to 15 percent of the manufacturer's market.

The bill's third section would call on VA to conduct a study relating to VA's experience under this measure to lay the foundation for a report to Congress to be furnished within a year after enactment. That requirement also calls on the Department to report on the status of contract negotiations with manufacturers, to include identification of negotiations which reach an impasse. The Committee envisions that this report requirement will help insure that parties approach negotiations with the aim of arriving at fair, reasonable prices.

Oversight Findings

No oversight findings pertaining to the subject of this bill have been submitted to the Committee by the Committee on Government Operations

Congressional Budget Office Cost Estimate

The following letter was received from the Congressional Budget Office concerning the cost of the reported bill:

Congressional Budget Office
U.S. Congress,
Washington, DC, November 21, 1991.

Hon. G.V. Montgomery,
Chairman, Committee on Veterans' Affairs,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2890, as ordered reported by the House Committee on Veterans' Affairs, November 13, 1991. The bill would affect in several ways the prices paid for outpatient drugs by federal health-care programs. The effects of H.R. 2890 on the Medicaid program would affect direct spending and thus would be subject to pay-as-you-go procedures under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985. As a result, the estimate required under clause 8 of House Rule XXI also is attached.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert D. Reischauer,
Director.

Enclosure
1. Bill number: H.R. 2890

2. Bill title: None.

3. Bill status: As ordered reported by the House Committee on Veterans' Affairs, November 13, 1991.

4. Bill purpose: This bill would affect in several ways the prices paid for outpatient drugs by federal health-care programs. Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA-1990) requires that, in order for a state to receive federal reimbursement for Medicaid drug purchases, drug manufacturers must agree to give rebates to state Medicaid programs. The amount of the rebate on a drug is based on a complex calculation of several factors including the manufacturer's "best price" for the drug, i.e., the lowest price offered to any wholesaler, retailer, nonprofit entity, or federal entity.

In the case of many drugs, the best price is that of the Federal Supply Schedule (FSS) for drugs and pharmaceuticals. The FSS, administered by the Department of Veterans Affairs (VA), is a price catalog of about 10,000 pharmaceutical and drug items, from which VA, DoD, and other federal agencies can purchase drugs. H.R. 2890 would exempt FSS prices from the best price definition.

In addition, H.R. 2890 would roll back the prices that manufacturers can charge VA for outpatient drugs to their September 1, 1990 level. Price increases would be allowed equal to the inflation assumed for the VA Medical Care account in the President's budget request, or price increases could be determined by some other unspecified method. Manufacturers would be required to abide by this provision in order for the purchase of these products to be federally matched in the Medicaid program.

Finally, H.R. 2890 would return to the FSS any drugs that had been removed by manufacturers since January 1, 1990. The removal of a drug from the FSS would cause the VA and other federal purchasers to obtain the drug through considerably more expensive open market transactions.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1992	1993	1994	1995	1996
Direct Spending:					
Medicaid					
Budget Authority	0	15	0	0	0
Outlays	0	15	0	0	0
Authorization:					
VA Medical Care					
Estimated Authorization Level	− 110	− 120	− 130	− 140	− 150
Outlays	− 110	− 120	− 130	− 140	− 150
DOD Medical Care					
Estimated Authorization Level	− 80	− 90	− 100	− 110	− 110
Budget Authority	− 80	− 90	− 100	− 110	− 110
Total Authorization					
Estimated Authorization Level	− 190	− 210	− 230	− 250	− 260
Budget Authority	− 190	− 210	− 230	− 250	− 260

Basis of Estimate

The provision of H.R. 2890 that would exclude FSS prices from the best price determination would increase the cost of drugs to the

Medicaid program in those cases where the FSS price is currently the best price. The fiscal year 1992 effects of this provision have already been mandated by section 520 of P.L. 102-139, the VA-HUD Appropriation Act. The P.L. 102-139 provision, however, would exclude FSS prices from the best price calculation only through the earlier of June 30, 1992, or the enactment date of legislation concerning the price paid by the VA for drugs and biologicals. The direct spending estimate shown above reflects the cost to the Medicaid program occurring after July 30, 1992.

The amount of the increase in Medicaid costs from excluding FSS prices from the best price calculation would depend on the proportion of drugs for which the FSS price is the lowest, and on the difference between the FSS price and the next best price. Drug companies are currently preparing reports for the Health Care Financing Administration (HCFA) that will show the lowest price offered for each drug. These reports will eventually enable us to determine the proportion of drugs for which the FSS price is the best price, but they will not be available for several months. It is unlikely that data will ever be available on the second-best price for a drug.

The above estimate of the Medicaid cost increase is based on data from the state of California, showing, for a list of 31 commonly supplied drugs, the best price available in 1989. For 25 of the 31 drugs, the FSS price was the lowest price found. This estimate, therefore, assumes that, while the FSS does not always reflect the best price for a drug, it is an important component of the best price determination established by OBRA-1990. The relative weight given to this component in the estimate was based on discussions with HCFA actuaries and other knowledgeable people in the field.

The Medicaid effects of this provision are estimated to phase out quickly for two reasons. First, we have assumed that drug manufacturers would limit the discounts given to the government and others as a result of the required Medicaid rebates, thereby raising the best price over time. Second, the rebate is based on a dual calculation. It is set equal to the larger of (1) a best price discount or (2) a flat percentage discount, adjusted for increases in the average manufacturers drug price that exceed the increases in the Consumer Price Index (CPI). Because drug prices have tended to rise more rapidly than the CPI, the adjusted flat rate rebate will grow over time while the best price rebate is assumed to decline. Because the larger of the two rebates applies, we expect that virtually all rebates will be based on adjusted flat rates after 1993, and the effects of changes in the best price calculation will cease to be significant.

The other two provisions of H.R. 2890—the limitation of FSS drug prices increases to the level of inflation in the VA Medical Care account and the return to the FSS of any drugs removed by manufacturers since January 1, 1990—would primarily affect VA and DoD spending.

According to preliminary data from VA, FSS drug prices had risen from 1990 levels by 18-21 percent as of January, 1991. Since all drug purchase contracts had not been rewritten at that time, further price increases could occur. This estimate assumes that the

net price increase in 1991 will be 19.5 percent. Drug price increases in the out-years were assumed to follow historical trends.

If FSS drug prices in 1992 were recalculated to equal the 1990 level inflated only by the rate assumed for the Medical Care account, VA would reduce spending on drugs by around $110 million in 1992. DoD savings in 1992 are estimated at around $80 million. This amount is considerably higher than the subsequent year-to-year increases for two reasons: the 1992 savings represents the capping of two years of inflation, and in one of those two years, 1990, the increase in prices was unusually high.

No data are available for VA or other sources concerning the number of drugs that have been removed from the FSS since January, 1990. Thus, it is not possible to estimate the effects of this provision at this time.

6. Pay-as-you-go considerations: The Budget Enforcement Act of 1990 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1995. The bench mark against which changes in direct spending or receipts are measured in the baseline as described in the Act.

Because VA and DoD spending for pharmaceuticals is paid from appropriated accounts, only the effects of H.R. 2890 on the Medicaid program would affect direct spending. The Medicaid spending that would result from H.R. 2890 is not included in the baseline; thus, the bill would have the following pay-as-you-go impact:

[By fiscal years, in millions of dollars]

	1992	1993	1994	1995
Outlays	0	15	0	0

7. Estimated cost to state and local government:

The Medicaid program is jointly funded by the federal government and by state and local governments. State and local government spending would increase by an estimated $10 million in 1993 as a result of increasing Medicaid costs.

8. Estimate comparison: None.

9. Previous CBO estimate: None.

10. Estimate prepared by: K.W. Shepherd, Charles Seagrave, and Scott Harrison (226–2820)

11. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

CONGRESSIONAL BUDGET OFFICE ESTIMATE [1]

The applicable cost estimate of this Act for all purposes of section 252 and 253 of the Balanced Budget and Emergency Deficit Control Act of 1985 shall be as follows:

[By fiscal years, in millions of dollars]

	1992	1993	1994	1995
Change in Outlays	0	15	0	0
Change in Receipts	Not applicable			

[1] An estimate of H.R. 2890 as ordered reported by the House Committee on Veterans' Affairs on November 13, 1991. This estimate was transmitted by the Congressional Budget Office on November 21, 1991.

Inflationary Impact Statement

The reported bill would have no inflationary impact.

Department Report

On August 2, 1991, the Committee requested the official views of the Department of Veterans Affairs on the reported bill. As of the date the report was filed, the Committee had not received such views. However, the following letter dated August 22, 1991, from Secretary Derwinski to the Honorable John D. Dingell expresses the Department's views on the need for legislation on this subject:

Department of Veterans Affairs
The Secretary of Veterans Affairs,
Washington, DC, August 22, 1991.

Hon. John D. Dingell,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

Dear Mr. Chairman: As you know, the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) contained provisions to reduce pharmaceutical costs to the Medicaid program. Pharmaceutical manufacturers are now required to provide monetary rebates to the states—the aim being that prices to Medicaid match the "best price" i.e., lowest price accorded to any purchaser in the marketplace.

An unfortunate, though surely unintended, outcome of this legislation was sudden and sweeping drug price increases to Federal Departments and Agencies which procure drugs, the Department of Veterans Affairs being the primary one. It was commonly known that VA, until the enactment of OBRA 90, was a successful negotiator of discounted prices, which is not surprising since our price negotiations with manufacturers are completely centralized, we are an exceptionally large single purchaser, and pharmaceutical usage by VA provides manufacturers with exposure to 50 percent of this nation's physicians-in-training.

While VA had anticipated some cost shifting to result from this legislation, we were surprised by its magnitude. Naturally, there was no way to have anticipated this dramatic rise in pharmaceutical prices when we developed the medical care budgets for fiscal year 1991 and 1992. We now know the cost impact is so severe it cannot be dealt with by the administrative means available to us.

VA is now conducting a comprehensive study of cost and utilization statistics for all pharmaceutical items procured by VA on contract through the depot and the Federal Supply Schedules (FSS). This data, being collected systematically for the first time, will pro-

vide the accurate and valid numbers needed for a reliable cost impact analysis. Based on our findings thus far, VA can already demonstrate a substantial cost impact. The additional cost increases that are discovered as this exercise continues will be added, cumulatively, to the current total. Notably, VA has not yet begun to identify the additional costs associated with those items which were previously listed on the FSS, but because the manufacturer has chosen not to enter into a contract with VA, are currently being purchased on the open market with no negotiated price agreement.

Clearly, some mechanism needs to be made available to assist VA in controlling its pharmaceutical expenditures, while at the same time allowing VA to continue to provide medically necessary pharmaceuticals to patients. Several legislative proposals have been introduced in an effort to provide some relief from the unprecedented cost increases experienced by the Federal government. Given that the OBRA provision indirectly encourages price increases to VA, stabilization of prices at the pre-OBRA levels and a restoration of marketplace conditions that would allow VA to negotiate unencumbered with manufacturers for fair prices would be indicated.

Exclusion of all Federal prices from the calculation of "best price" as described in OBRA 90 would eliminate the incentive for manufacturers to escalate prices to their Federal customers. To minimize the additional costs already experienced, VA should have the opportunity to procure pharmaceuticals through FSS or depot at the contract prices in place prior to enactment of OBRA, with an allowance for inflationary price increases. Finally, current pharmaceutical prices to Federal customers have now been inexorably linked to Medicaid through OBRA, so manufacturers will need some incentive to enter into new contracts with VA. One possible way to provide that incentive would be to make participation in the Medicaid rebate program contingent upon entering into new, equitable agreements with VA.

I understand that there is some concern in your committee that excluding Federal prices from the "best price" formula would somehow jeopardize Medicaid's prices. However, we have reason to believe that other large buying groups receive discounts comparable to VA's and those purchasers could similarly serve the purpose of reducing Medicaid's prices.

I hope that you will understand our concern for maintaining the ability of VA's already strained medical care delivery system to adequately serve those who conscientiously serve our nation, and that you will support our efforts to prevent pharmaceutical cost shifting among Federal programs, consistent with the intent of OBRA 90.

Sincerely,

EDWARD J. DERWINSKI.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omit-

ted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTION 1927 OF THE SOCIAL SECURITY ACT

PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a [manufacturer).] *manufacturer) and an agreement described in paragraph (5) (with respect to drugs dispensed on or after the date of the enactment of that paragraph).*

* * * * * * *

(5) LIMITATION ON PRICES OF DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS.—

(A) AGREEMENTS WITH SECRETARY.—An agreement under this paragraph is an agreement—

(i) between the Secretary of Veterans Affairs and a manufacturer of covered outpatient drugs that provides that, with respect to a drug described in subparagraph (B) procured in a calendar quarter, the price for the drug charged to the Department of Veterans Affairs may not exceed the applicable price for the drug charged to the entity as of September 1, 1990, increased (in a compounded manner) by the sum of the covered drug updates (as defined in subparagraph (C) for calendar quarters beginning on or after April 1, 1991, up to and including the calendar quarter during which the drug is procured; or

(ii) between the Secretary of Veterans Affairs and a manufacturer of covered outpatient drugs that provides for another methodology for determining the prices charged to the entity by the manufacturer for drugs described in subparagraph (B).

(B) DRUGS COVERED UNDER AGREEMENTS.—Subparagraph (A) shall apply to any drug or biological product procured by the Department of Veterans Affairs—

(i) that is purchased under a depot contracting system; or

(ii) that is listed under the Federal Supply Schedule of the General Services Administration on or after January 1, 1990.

(C) COVERED DRUG UPDATE.—For purposes of subparagraph (A)(i), a "covered drug update" is equal to, with respect to a calendar quarter, 25 percent of the percentage increase provided for calculating the cost of inflation in the medical care account of the Department of Veterans Affairs contained in the budget request submitted by the Secretary of Veterans Affairs for the fiscal year in which the calendar quarter occurs.

(D) EFFECTIVE DATE.—Subparagraph (A) shall apply to drugs and biological products procured by the Department of Veterans Affairs on or after the date of the enactment of this paragraph.

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(c) AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—With respect to single source drugs and innovator multiple source drugs, each manufacturer shall remit a basic rebate to the State medical assistance plan. Except as otherwise provided in this subsection, the amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to each dosage from and strength of single sources drugs and innovator multiple source drugs shall be equal to the product of—

(A) * * *

* * * * * * *

(C) For the purposes of this paragraph, the term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or [governmental entity] *governmental entity (other than an entity of the Federal Government)* within the United States [(excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government)]. The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section) and shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount;

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